



DEPARTMENT ON DISABILITY SERVICES
DEVELOPMENTAL DISABILITIES ADMINISTRATION
HEALTH CARE BULLETIN
Issued: May 6, 2009

Metoclopramide (Reglan)

Audience: Health Care Professionals

The Food and Drug Administration has issued the following warning for the use of Metoclopramide (Reglan):

FDA notified healthcare professionals that manufacturers of metoclopramide (Reglan), a drug used to treat gastrointestinal disorders, must add a boxed warning to their drug labels about the risk of its long-term or high-dose use. Chronic use of metoclopramide has been linked to tardive dyskinesia, which may include involuntary and repetitive movements of the body, even after the drugs are no longer taken. These symptoms are rarely reversible and there is no known treatment. Metoclopramide is available in a variety of formulations including tablets, syrups and injections. Names of metoclopramide-containing products include Reglan Tablets, Reglan Oral Disintegrating Tablets, Metoclopramide Oral Solution, and Reglan Injection. Manufacturers will be required to implement a risk evaluation and mitigation strategy [REMS] to ensure patients are provided with a medication guide that discusses this risk. Current product labeling warns of the risk of tardive dyskinesia with chronic metoclopramide treatment. For more information visit the FDA website at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Metoclopramide>.

Additional Information about Metoclopramide (Reglan):

- Metoclopramide comes as a tablet and liquid to take by mouth;
- Directions on the prescription label should be carefully followed;
- Metoclopramide should be taken exactly as directed by your physician.

Before taking Metoclopramide you should tell your physician and pharmacist:

- Of any prescription and nonprescription medications that are being taken;
- If you are taking amobarbital (Amytal), insulin, narcotics (pain medications), Phenobarbital, sedatives, tranquilizers and vitamins;
- If you are allergic to Metoclopramide;
- If you have or ever had an adrenal tumor, seizure disorder, Parkinson's disease, high blood pressure; heart, liver, or kidney disease; a history of mental illness or depression; or an intestinal blockage or bleeding; and
- If you are having surgery, including dental surgery.



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Side Effects

Side effects include drowsiness, restlessness, fatigue, constipation and diarrhea.

Other symptoms

If you experience involuntary movements of the limbs or eyes; spasm of the neck, face and jaw muscles; or changes in mood (depression), **call your physician immediately.**

Additional information and resources:

US Food and Drug Administration

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=86#3>

National Institutes of Health

<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a684035.html>

Mayo Clinic

<http://www.mayoclinic.com/health/drug-information/DR600921>